IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDPOINTE HEALTHCARE INC.,	)	
	)	
Plaintiff,	)	C.A. No. 06-164 (SLR)
	)	
v.	)	
	)	
APOTEX INC. and APOTEX CORP.,	)	
	)	
Defendants.	)	

APOTEX'S MEMORANDUM IN SUPPORT OF ITS MOTION TO SUPPLEMENT APOTEX'S RESPONSE BRIEF ON CLAIM CONSTRUCTION

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Apotex Inc. and Apotex Corp.

Dated: February 26, 2008
850967 / 30136

In Apotex's Response To MedPointe's Opening Brief On Claim Construction Issues ("Apotex's Response Brief"), Apotex respectfully requested leave to supplement the record with official Hague Convention Testimony that was unavailable at the time of filing its brief. Apotex now seeks leave of the Court to supplement that testimony.

In addition, Apotex respectfully requests the Court allow Apotex to supplement the record in response to MedPointe's assertion, raised for the first time in MedPointe's Response Brief On Claim Construction Issues ("MedPointe's Response Brief") that Apotex's proposed claim construction would require the Court to find "the '194 patent somehow includes the world's first eye spray." MedPointe's Response Brief, p. 24. MedPointe's attempt to argue for the first time that eye sprays have been heretofore entirely unknown is improper. In response, Apotex requests the Court's permission to present evidence that, not only are eye sprays known in the art, but they were known in the art long before November 1987, the priority date of MedPointe's patent.

Apotex sought to confer with MedPointe regarding its motion. MedPointe offered to consent to Apotex's supplementing the record with official Hague Convention testimony if it were provided an opportunity to review Apotex's memorandum. MedPointe refused to consent to Apotex's supplementation necessitated by MedPointe's over-ambitious and late arguments regarding the historical use of eye sprays. Given MedPointe's objections, Apotex informed counsel that it would not oppose MedPointe's responding to Apotex's supplementation, if it saw fit to do so. However, Apotex saw no utility in having MedPointe delay the filing of its motion by reviewing the content in advance, since MedPointe would not consent to the supplementation in its entirety.

1. The Inventor's Testimony Demonstrates Tolerability, Safety and Efficacy Are Not Limitations of the '194 Patent

MedPointe attempts to incorporate safety, efficacy and tolerability into the claims of the '194 patent. On page 9 of Apotex's Response Brief, Apotex informed the Court that Helmut Hettche, the inventor of the '194 patent, testified in Germany on December 10, 2007 that nose and eye solutions - even those falling within the narrowest ranges of the '194 patent claims - caused intense burning when applied directly to the nose and eye. Because the official transcript of the inventor's testimony from the German Court was unavailable, Apotex was unable to quote Dr. Hettche precisely. The official transcript has now been made available to the parties and a certified translation has been obtained by Apotex.

During the Hague Convention proceeding, Dr. Hettche was asked about MedPointe production documents evidencing his self-administration of azelastine solutions directly to the nose. Dr. Hettche explained his self-administration[1]:

> Azelastin hydrochloride was the material for tablets. I thought why not simply spray this material into the nose? I asked my assistant to prepare an appropriate solution; I thought that 0.5% would be sufficiently low. I then filled the solution into a nose spray bottle, which I had retained from my use of DNCG. I had cleaned it. When I sprayed it into my nose, there was a terrible burning sensation.
> ...
> On the next weekend, I then took [a] 0.1% solution along again in order to put drops into my eye. I did so. There was a burning sensation initially, which abated after roughly one minute.

Ex. A, Hague Proceeding Transcript p. 14-15.[2] The inventor's testimony clearly establishes that, even within the narrowest concentration range of claim 4 of the '194 patent[3], azelastine

[1] MedPointe failed to produce documents relating Dr. Hettche's self-administration of azelastine directly to the eye (and thousands of other German language documents) until after claim construction briefing was complete (and two weeks before the originally scheduled trial date). MedPointe had previously assured the Court it had produced all such documents. Thus, prior to the Hague Convention Proceedings, Apotex was completely unaware that Dr. Hettche had self-administered azelastine eye drops as his testimony - and now, MedPointe documentation - shows.

containing medicaments applied directly to the nose and eye are not "safe, efficacious and tolerable." When applied directly to the nose, they cause "terrible burning sensation." When administered topically to the eye, they cause burning for roughly a minute.

The inventor did not write claims describing only "tolerable, safe and efficacious" methods, and the inventor himself knew that compositions described by the claims were not "tolerable, safe and efficacious" when applied directly to nasal tissues or to the conjunctival sac of the eye (*i.e.* some caused "terrible burning sensation"). Nevertheless, MedPointe still asks this Court interpret the terms "medicament" and "azelastine and its physiologically acceptable salts" to denote that use of the claimed method be "tolerable, safe and efficacious." Moreover, MedPointe makes no attempt to define "tolerable, safe and efficacious" for the Court. This Court should reject MedPointe's attempt at incorporating undefined terms into the claims of the '194 patent, especially when the ordinary meaning of those terms would describe non-enabled compositions.

2. Eye Sprays Were Known in the Art in November, 1987

In MedPointe's Opening Brief On Claim Construction Issues ("MedPointe's Opening Brief"), MedPointe argued claim 9 of the '194 patent was limited by the '194 patent specification

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[2] In Apotex's Response Brief, Apotex was forced to rely on unofficial translations obtained during the Hague Convention Proceedings, and inadvertently reported that burning lasted for 30 minutes, an unintentional error Apotex now corrects based on the certified translation attached hereto.

[3] Asserted claim 4 of the '194 patent has the narrowest azelastine concentration of the patent claims, describing a "medicament [that] contains 0.003 to 0.5% (weight/weight) of azelastine…." MedPointe's argument, however, requires the method of claim 2 to be just as "tolerable, safe and efficacious" as claim 4, even though it recites medicaments containing up to 2% azelastine, several fold more than the 0.5% medicament that caused a "terrible burning sensation" when applied to nasal tissues.

and prosecution history to a nasal spray.[4] MedPointe's Opening Brief, p. 25. In MedPointe's Response Brief, however, MedPointe disingenuously argued for the first time that the Court was required to limit the scope of claim 9 to nasal sprays or else find "the '194 patent somehow includes the world's first eye spray." MedPointe's Response Brief, p. 24 (emphasis added). MedPointe's attempt to argue for the first time in its response brief that eye sprays are unknown in history is improper.

Furthermore, eye sprays have been known in the art for decades, contrary to MedPointe's assertion. For example, U.S. Patent No. 3,314,426 ("'426 patent"), entitled "Eyecup and Spray Dispenser," issued to Albert Carroll in 1967. Ex. B. The '426 patent disclosed "a spray dispenser for supplying a medicament to the eye in the form of a finely divided spray or mist and in a relatively small but adequate, metered amount." Ex. B, Col. 1, ln. 64-67. In 1970, U.S. Patent No. 3,506,001 issued to assignee the Colgate-Palmolive Co. and is titled "Eye-Spraying Device Having Mirror." Ex. C. The invention "relates to administering medicated solutions to the eye and, more particularly, to spray devices for administering medicated solutions to the eye[.]" Ex. C, Col. 1, ln. 20-23. Contrary to MedPointe's argument, it is clear that as of November 1987, applying medicaments to the eye in the form of a spray was well known. Furthermore, devices describing methods of applying a medicament spray to the eye continue to be patented - as evidenced by U.S. Patent No. 5,588,564 issued on Dec. 31, 1996 and titled "Eye Spray Mist Dispenser," Ex. D - and basic literature searches return publications relating to the application of medicaments to the eye in the form of drops and sprays. *See e.g.* Muller F., *et al*

[4] MedPointe also presented testimony from Dr. Schwartz (a physician) evidencing he was unaware of an available eye spray for allergy. Whether an eye spray for allergy was available for Dr. Schwartz to prescribe is a different matter entirely from the argument raised by MedPointe for the first time in its response brief that eye sprays are unknown in history.

Comparative in vitro investigation of the forces exerted by eye drops and eye spray; Pharmazie 2005 Aug; 60(8):630-1 (publicly available).

In view of this evidence, MedPointe's baseless and late argument that Apotex advocates the Court somehow recognize the world's first eye spray should be rejected. While it may be true that the preferred spray of the '194 patent was a nasal spray - "The preferred embodiment of the invention is a sterile and stable aqueous solution of azelastine or one or more of its salts which can be used in the form of … a spray (preferably a nasal spray)", col. 2, ln. 12-17 - patent claims are not limited to their preferred embodiments.

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Dated: February 26, 2008
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Kenneth L. Dorsney, hereby certify that on February 26, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on February 26, 2008, the document was Electronically Mailed to the following person(s)

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EXHIBIT A

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30 AR 4/07 Offenbach am Main, Montag, 10.12.2007

Nicht - ÖFFENTLICHE VERHANDLUNG DES AMTSGERICHTS

vor

Richter Dr. Marienfeld

ohne Urkundsbeamtin/Urkundsbeamten
unter Verwendung eines Tonbandes

In der Rechtshilfesache

MedPointe Healthcare Inc. gegen Apotex, Inc. u. a.

erschien(en) bei Aufruf der Sache:

für die Klägerin : Rechtsanwältin Toker von der Kanzlei Kirkland & Ellis LLP
für die Beklagten : RA Dr. Pitz
sowie die Rechtsanwälte Sodikoff & Benson von der Kanzlei Welsh & Katz, Ltd.

Der Zeuge Dr. Hettche mit den Rechtsanwälten Herrn Michael von der Kanzlei Paul Hastings Attorneys und Rechtsanwältin Dr. Nacimiento

Desweiteren sind erschienen die Dolmetscher Frau Glasmann und Frau Hautum sowie Herr Granatta.

Die Parteien verständigen sich darauf, dass die jeweiligen Antworten nicht simultan übersetzt werden sondern direkt im Anschluss.

Das Gericht weist darauf hin, dass die Sitzung ausschließlich in deutscher Sprache geführt werden wird.

Erläuterungen zu gebräuchlichen Abkürzungen in Sitzungsprotokollen

VU	= Versäumnisurteil	RB	= Rechtsbeistand	b.u.v.	= beschlossen und verkündet
VB	= Vollstreckungsbescheid	Ss	= Schriftsatz	lt. d. u. g.	= laut diktiert und genehmigt
VT	= Verkündungstermin	KlV	= Klägervertreter	v. u. g.	= vorgelesen und genehmigt
RA	= Rechtsanwalt	BeklV	= Beklagtenvertreter	n. v. u. n. v.	= nicht verwandt und nicht verschwägert

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Ich habe es gesehen im November 2007 nach Zusendung durch das Gericht. Gelesen habe ich es nicht. Ich habe es davor auch nicht außerhalb der Kommunikation mit Herrn Dr. Bezold gelesen. Es sei eingeschränkt, dass damit nicht gesagt werden soll, dass ich es im Rahmen der Kommunikation mit Dr. Bezold gelesen habe.

Ich habe die für mich relevanten Teile gelesen, aber nicht das gesamte Patent; dies bei Dr. Bezold.

Die Kommunikation mit Dr. Bezold hat im Rahmen des Einspruchsverfahrens stattgefunden.

Im allgemeinen Einvernehmen wird auf die Beantwortung der Fragen F 9 bis 12 sowie F 17 verzichtet.

Zu F 13 :

Ich kam dazu, da ich zu der Zeit sehr stark an Heuschnupfen litt. Verbunden damit waren auch die genannten Augenaffektionen, insbesondere wenn ich auf dem Lande war. Wir arbeiteten ja damals mit Azelastin in der Asthmaforschung. Mir war bekannt, dass es sich dabei um ein Antihistamin handelt. Von Antihistaminen war mir allerdings bekannt, dass sie als Nebenwirkung hatten, dass man furchtbar müde davon wurde. Ich selbst habe zur Anwendung lediglich DNCG (Dinatriumchromoglykat) genommen. Dabei handelt es sich allerdings um ein Mittel, das man sehr häufig nehmen musste und das eine sehr schwache Wirkung hatte. Und die orale Anwendung kam für mich ohnehin nicht in Betracht, da dabei bei mir eine unbezwingbare Müdigkeit auftrat, so dass ein Arbeiten dann nicht möglich war.

Wir hatten im Labor Azelastinhydrochlorid wegen unserer Forschung. Ich war damals Herstellungsleiter für klinische Prüfmuster. Bei dem Azelastinhydrochlorid handelt es sich um den Wirkstoff für die Tabletten. Ich dachte mir, warum nicht einmal diesen Wirkstoff in die Nase sprühen ? Ich bat meinen Assistenten, eine entsprechende Lösung herzustellen, ich dachte 0,5 % müsste ausreichend niedrig sein. Die Lösung füllte ich dann in ein

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Nasensprayfläschchen, das ich noch hatte wegen meiner Anwendung mit DNCG. Ich hatte dies gereinigt. Als ich die Lösung in meine Nase sprühte, trat ein fürchterliches Brennen auf.

Trotzdem nahm ich diese Lösung mit ins Wochenende. Es war damals Freitag, daran kann ich mich noch erinnern. Ich fuhr damit zu meiner Freundin auf dem Lande und hatte vor, dort den Effekt der Lösung auf die Behandlung von Heuschnupfen auszutesten. Der Effekt war hervorragend. Ich konnte eine ganztägige Wanderung machen, ohne dass Symptome des Heuschnupfens aufgetreten wären.

Auf Nachfrage Mr. Bensons :

Das war ungefähr im Juni 1985.

Dann bat ich meinen Laboranten eine Lösung mit 0,1 % herzustellen, um festzustellen, ob dann das Brennen wieder auftreten würde, was nicht der Fall war.

Ich nahm dann diese Lösung mit am nächsten Wochenende zu meiner Freundin. Ich wollte die Effektivität des Produktes prüfen. Und es stellte sich bei gleicher Effektivität wie bei der 0,5prozentigen Lösung keinerlei Nebenwirkungen ein, wie z.B. Müdigkeit oder bitterer Geschmack.

Am nächsten Wochenende nahm ich die 0,1prozentige Lösung wieder mit, um sie ins Auge zu tropfen. Dies habe ich getan. Es trat zunächst ein Brennen auf, das nach ungefähr 1 Minute abgeklungen war. Danach war die Effektivität des Mittels wiederum sehr gut. Das war der Selbstversuch. Das bewog mich zu sagen : Donnerwetter, daraus müsste man 2 Präparate machen.

Zu F 14 :

Zuerst Heuschnupfen und dann später auch einen banalen Schnupfen. Das war dann ein weiterer Selbstversuch.

30 AR 4/07 Offenbach am Main, Monday, 10 Dec. 2007

Closed HEARING OF THE AMTSGERICHT [MUNICIPAL COURT]

Dr. Marienfeld, Judge, presiding

without court reporter
using tape recorder

In the case of legal assistance

MedPointe Healthcare Inc. vs. Apotex, Inc. et al

the following persons were present, when the case was called:

For the plaintiff: Mrs. Toker, attorney-at-law, of the law firm Kirkland & Ellis LLP

For the defendant: Dr. Pitz, attorney-at-law, and Sodikoff and Benson, attorneys-at-law, of the law firm Welsh & Katz, Ltd.

The witness Dr. Hettche, with Mr. Michael, attorney-at-law, of the law firm Paul Hastings Attorneys, and Dr. Nacimiento, attorney-at-law.

Furthermore, Mrs. Glasmann, Mrs. Hautum, and Mr. Granatta as interpreters.

The parties agree that the respective answers will not be translated simultaneously, but consecutively.

The Court points out that the hearing will be held exclusively in German.

Regarding question F 8, first and second question, the witness answers:
I also do not wish to say anything about this, because this was also a component of the discussion with Dr. Bezold.

Regarding the third question of F8:

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I saw that in November 2007 after receiving it from the Court. I did not read it. Prior to that time, I had not read it outside the communication from Dr. Bezold. By way of limitation, this is not to say that I read it during the communication with Dr. Bezold.

I read the parts relevant for me, but not the entire patent; that at Dr. Bezold's.

The communication with Dr. Bezold took place within the framework of the opposition process.

With the concurrence of all participants, the requirement to answer is waived for question F 9 to 12 and F 17.

Regarding question F 13:
I did so, because I suffered very badly from hay fever at that time. That also included the specified eye effects, particularly when I was in a rural area. After all, we worked with azelastin in asthma research at that time. I did know that it was an antihistamine. However, I knew about antihistamines that they have a side effect of making you very tired. I myself used only DNCG (dinatrium chromoglykat). But that is a compound that needs to be taken very frequently and that has a weak effect. And the oral application did not apply in my case anyway, given that it made me so terribly tired that it precluded working.

We had azelastin hydrochloride in the lab for our research. I was then in charge of the production of clinical testing material. Azelastin hydrochloride was the material for tablets. I thought why not simply spray this material into the nose? I asked my assistant to prepare an appropriate solution; I thought that 0.5% would be sufficiently low. I then filled the solution into a

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nose spray bottle, which I had retained from my use of DNCG. I had cleaned it. When I spayed it into my nose, there was a terrible burning sensation.

Nonetheless, I took the solution home for the weekend. I do remember that it was a Friday. I took it along on a visit to my girl friend out in the rural area and I had the plan to test the impact of the solution in the treatment of hay fever. The impact was excellent. I could go on a full-day hike without suffering any symptoms of hay fever.

After follow-up question by Mr. Benson:
That was approximately during June 1985.

I then asked my lab assistant to prepare a solution with 0.1% in order to test whether the burning sensation would reoccur, which was not the case.

I then took this solution along on a visit to my girl friend on the following weekend. I wanted to test the effectiveness of the product. And at equivalent effectiveness as for the 0.5% solution, there were no side effects, such as tiredness or bitter taste.

On the next weekend, I then took the 0.1% solution along again in order to put drops into my eye. I did so. There was a burning sensation initially, which abated after roughly one minute. Once again, the effectiveness of the compound was very good after that. That was the self-trial. It caused me to say: Yes, indeed, one should produce this in two forms.

Regarding F 14:
First hay fever and then a common cold. That was then another self trial.

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With the concurrence of all participants, the requirement to answer is waived for question F 15.

Regarding F 16:
The symptoms related to hay fever, i.e. conjunctivitis, tearing, red eyes and itching.

The hearing is then recessed for 30 minutes.

The hearing is then started again.

With the concurrence of all participants, the requirement to answer is waived for question G 1 and 2.

Regarding G 3, first question:
No.

Second question:
I first learned of this when I worked on question G3 now in 2007.

Regarding question 3, G 3:

Page 17

No.

EXHIBIT B

April 18, 1967 A. CARROLL 3,314,426

EYECUP AND SPRAY DISPENSER

Filed May 20, 1964 2 Sheets-Sheet 1

FIG.1.

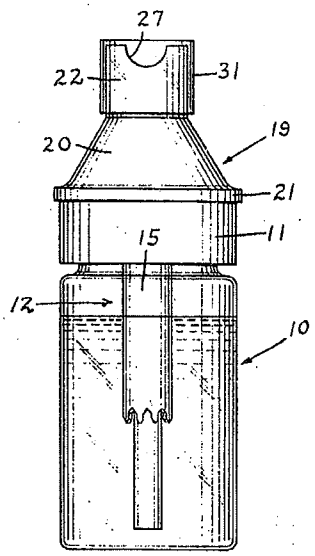


FIG.2.

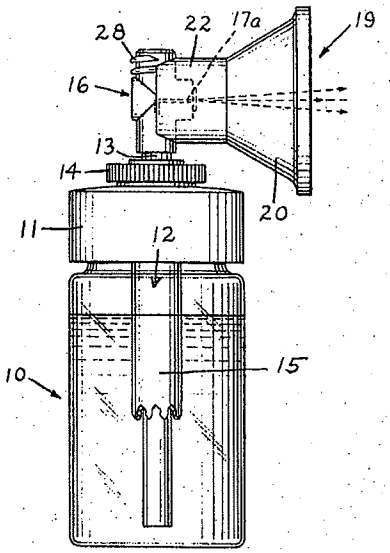


FIG.4.

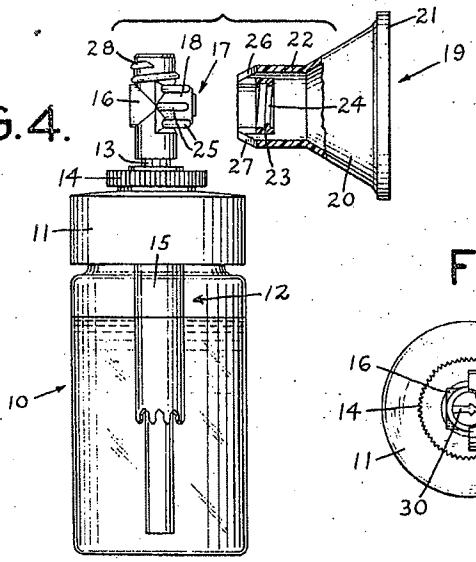
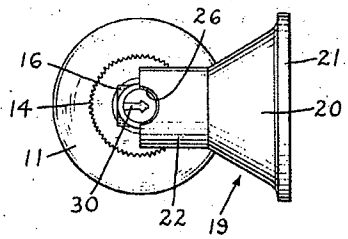


FIG.3.



INVENTOR
ALBERT CARROLL
BY
Brumbaugh, Free, Graves & Donohue
HIS ATTORNEYS

April 18, 1967 A. CARROLL 3,314,426

EYECUP AND SPRAY DISPENSER

Filed May 20, 1964 2 Sheets-Sheet 2

FIG.5.

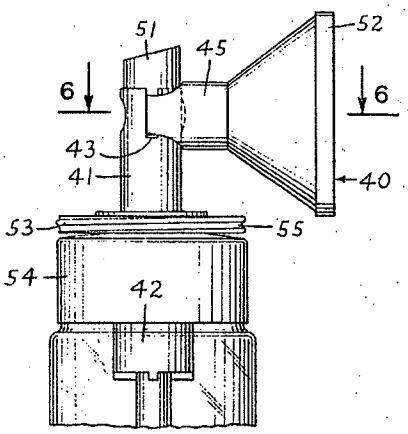


FIG.7.

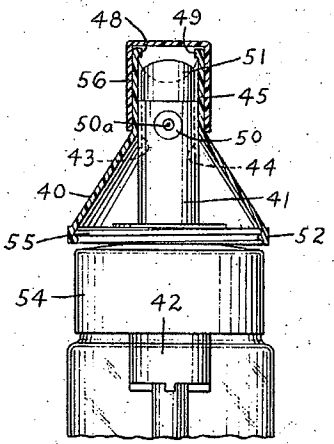
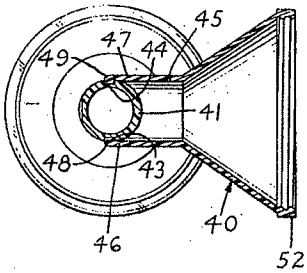


FIG.6.



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United States Patent Office 3,314,426 Patented Apr. 18, 1967

3,314,426

EYECUP AND SPRAY DISPENSER

Albert Carroll, Hartsdale, N.Y., assignor to Lever Brothers Company, New York, N.Y., a corporation of Maine

Filed May 20, 1964, Ser. No. 368,844
4 Claims. (Cl. 128—173)

ABSTRACT OF THE DISCLOSURE

This invention relates to a combined eyecup and spray dispenser having a plunger actuator for discharging a medicament through a laterally directed nozzle, the eyecup serving as a cover for the plunger and nozzle and adapted to be mounted on the nozzle to form an eyecup and shield and providing an illuminated target for attracting the eye so that medicament discharged from this nozzle can be directed into the center of the eye without involuntary blinking of the eye.

This invention relates to medication apparatus and relates particularly to apparatus for applying a medicament to the eyes, for laving the eyes and for treating eye diseases, infections, irritations, strain and the like.

The most common device for applying a medicament to the human eye is an eyecup formed of glass, plastic, metal or the like. While such eyecups have been used satisfactorily for the treatment of eyes, they are not without disadvantages. For example, in the hands of an unskilled user, the medicament frequently leaks or is spilled from the eyecup as it is applied to the eye. Moreover, the liquid in the eyecup is in a more or less quiescent state which renders it somewhat ineffective for removal of foreign particles or bodies from the eye. Because of these deficiencies of the ordinary eyecup, it has been proposed, heretofore, to provide eyecups with means for spraying a liquid into the eye of the user. For example, the container associated with the eyecup may be a squeeze bottle or provided with a syringe bulb, a pump or the like for squirting the medicament into the eye. These devices are not very satisfactory for the reason that a stream of the medicament is discharged with considerable force and volume into the eye. While in theory, the use of such a forceful stream will dislodge a foreign particle from the eye, in actual practice, the stream or jet causes the user to blink, with the result that the medicament may not reach the eye to exert its full washing effect.

Moreover, inasmuch as a relatively large volume of medicament is discharged into the eye, the eyecup must be applied tightly to the area around the eye to prevent leakage and careful handling is required to avoid spillage after use. Leakage can occur also due to inadvertent squeezing of the container or other actuating device during handling, shipping and the like.

The prior devices also are somewhat unwieldy for the eyecup usually extends outwardly from the container making its use, packaging and handling difficult.

Contamination of the prior dispensing eyecups by dust can occur for the reason that their inner surfaces are unprotected when not in use.

In accordance with the present invention, the difficulties and disadvantages of the prior devices are overcome by providing a spray dispenser for supplying a medicament to the eye in the form of a finely divided spray or mist and in a relatively small but adequate, metered amount. The dispenser has a shield to be applied over the eye to confine the spray to the eye area, the shield being removable and storable in a protective relation to the actuator by means of which the medicament is dispensed and with the inner surface of the eye shield protected from contamination.

More particularly, the new dispensing device includes a container for a medicament and a device for discharging the medicament from the container including an actuating member which extends through the top or cover of the container and is provided with a laterally facing orifice of very small diameter, e.g. about 0.01 of an inch through which the medicament is discharged in the form of a spray or mist. The eye shield is constructed and arranged so that it can be attached to and detached from the nozzle and can also be stored on the upper end of the actuating member in such a position that the open end of the eye shield engages the cover for the container and covers and protects the orifice as well as the inner surface of the eye shield and retains the actuating member against movement so that it cannot be operated inadvertently to cause discharge of a medicament from the container.

In use, the eye shield is attached to the lateral extension containing the orifice or nozzle and can either be brought adjacent to the eye or lightly into contact with the area around the eye. Upon movement of the actuating member, a small amount of the medicament is discharged in the form of a fine mist or spray directly into the eye without such sharp impingement as to cause blinking of the eye. The amount of the medicament is small so that little if any of it escapes from the eye and accordingly, the device can be used with a minimum of difficulty, spillage or waste under almost any circumstances.

For a better understanding of the present invention, reference may be had to the accompanying drawing in which:

FIGURE 1 is a front elevational view of a typical medicament dispenser of the type embodying the present invention with the eye shield attached to the top of the container in condition for shipment, handling or storage;

FIGURE 2 is a side elevational view of the dispenser with the eye shield attached to the dispenser for application of the medicament to the eye;

FIGURE 3 is a plan view of the device shown in FIGURE 2;

FIGURE 4 is an exploded side elevational and partial sectional view of the dispenser;

FIGURE 5 is a side elevational view of a modified form of eyecup dispenser shown partly broken away;

FIGURE 6 is a view in section taken on line 6—6 of FIGURE 5; and

FIGURE 7 is a front elevational view of the dispenser of FIGURE 5 with the eye shield in stored position and with parts broken away to disclose details thereof.

The spray dispenser shown for purposes of illustration in FIGS. 1 to 4 of the drawings includes a container or bottle **10** formed of a glass, plastic or the like having a cover **11** which may be connected permanently or detachably to the upper end of the bottle **10**. The cover **11** may be formed of plastic material or the like as desired. Mounted in the cover and extending downwardly into the container is a pump **12** of the plunger type such as that shown, for example, in U.S. Patent No. 2,362,080, dated November 7, 1944 and in my copending application Serial No. 260,216, filed February 21, 1963, now abandoned. The pump includes a piston (not shown) actuated by means of a plunger **13** which extends through the cover **11** and suitable check valves (not shown) which, upon downward movement of the plunger, cause a measured charge of the medicament to be discharged from the pump. Upon upward movement of the plunger **13** another charge of medicament is drawn into the pump. The pump plunger **13** is slidably received in a collar **14** which is mounted in the cover **11** of the container and carries the barrel or cylinder **15** of the pump which has its inlet near the bottom of the container.

On the upper end of the plunger **13** is a head **16** forming an actuator, the upper end of which may be pressed by a finger to cause a metered amount of medicament to be discharged through a nozzle **17** having an orifice **17***a* and comprising a projection or boss **18** extending laterally from the head **16**. The nozzle **17** is disposed midway between the upper and lower ends of the actuating head and is adapted to receive an eye shield **19** thereon.

As best shown in FIGURES 2, 3 and 4, the eye shield **19** includes a conical portion **20** having a rim **21** at its larger end adapted to engage the area around an eye and also, as shown in FIGURE 1, to engage the periphery of the cover **11** of the container.

A tubular sleeve portion **22** extends from the smaller diameter end of the conical portion **20** and has an internal annular surface **23** provided with internal threads **24** which are adapted to frictionally engage the ribs **25** on the extension **18**. Diametrically spaced arcuate notches **26** and **27** are formed in the end of the sleeve **22** so that it fits snugly against the side of the actuator **16**.

Inasmuch as the ribs **25** extend outwardly from the extension **18**, spaces are present between them through which light is visible from the interior of the shield **20** when the latter is in engagement with the face around the eye. The light forms a target for attracting the eye to enable the medicament to be directed into the center of the eye when the actuating member **16** is pressed. The eye shield need not be pressed tightly around the eye for the amount of medicament discharged preferably is relatively small in volume and accordingly, the excess, if any, which would run out of the eye is negligible.

As shown in FIGURES 2 and 3, the upper or outer end of the actuator **16** is provided with threads **28** which are adapted to mate with the threads **24** to allow the eye shield **20** to be stored on the end of the container as shown in FIGURE 1. Thus, the eye shield **20** may be removed from the nozzle extension **18**, inverted and then screwed on the upper end of the actuator **16** to engage the rim **21** with the cover **11**. In this position, the eye shield covers the nozzle **17** and locks the actuator **16** against movement. Moreover, the inner surface of the eye shield **19** and the nozzle **17** are protected against dust and other contamination.

It will be understood that other types of threads **24** and **28** or other types of fastening means such as, for example, a bayonet slot connection may be used for attaching the eye shield to the upper end of the actuator **16** or to the cover **11** when the eye shield is not in use.

For convenience in attaching the eye shield to the actuator **16**, the upper end of the actuator may have a suitable arrow **30** (FIG. 3) or other indicator pointing to the side where the eye shield should be attached.

As indicated above, the orifice in the nozzle **17** through which the medicament is discharged should be of such size as to cause the medicament to be discharged in a form of a mist or fog and to that end, the orifice preferably is between about 0.01 and 0.011 inch in diameter.

As a further protection for the dispenser, the upper end of the actuator and sleeve **22** of the eye shield may be covered by means of a cap **31** formed of plastic or the like which fits frictionally and detachably over the sleeve **22** of the eye shield.

By making the cover **11** removable from the container or the bottle **10**, it is, of course, possible to refill the container as may be required or, the cover may be secured permanently to the container forming a "throw away" unit.

Other means for mounting the shield on the dispenser in condition for use and for storing the shield are equally suitable. As shown in FIGURE 5, the shield **40** is clipped to the actuating head **41** of the pump **42**. Diametrically spaced grooves **43** and **44** are formed in the head and the cylindrical portion **45** of the shield **40** includes arms **46** and **47** having inwardly extending flanges **48** and **49** which can be snapped into or slipped into the grooves **43** and **44**. In this form of dispenser, the nozzle **50** and the orifice **50***a* therein are substantially flush with the surface of the plunger **41**. Also, the upper end portion **51** of the plunger is of reduced diameter so that the shield can be stored by slipping it over the plunger and the rim **52** of the shield either frictionally engaged with the collar **53** on the cap **54** or threaded on the threads **55** on the collar, as illustrated. If desired, the collar **53** can be omitted and the parts proportioned so that the rim **52** of the shield either frictionally engages the upper end of the closure cap **54** or engages threads thereon. With either structure, the tubular portion **45** extends sufficiently above the upper end of the actuating head **41** that it cannot be depressed accidentally when the shield is stored on the container. Protection against contamination is afforded by means of a cap **56** slidably received on the tubular extension **45** as shown in FIGURE 7.

Dispensers of the type described above can be readily packed in cartons, boxes or the like and can be shipped without danger of loss of the contents and without danger of contamination of the eye shield or those parts with which the medicament comes in contact. Moreover, when made in small sizes, the dispenser can be carried in pocket, purse or the like without danger of leaking or becoming contaminated and thus is available for use at any time. Inasmuch as only small increments of the medicament are discharged for treating an eye, it is unnecessary to take any precautions in the use of the device and accordingly, it can be used whenever and wherever required.

Many other variations and modifications of the dispenser are possible and accordingly, the form of the invention described herein should be considered illustrative.

I claim:

1. A spray dispenser comprising a container for a medicament, a cover for said container, means mounted on said cover and extending into said container and having a plunger for discharging medicament from said container, an actuator on said plunger, a nozzle in said actuator for directing a spray of said medicament laterally from said actuator upon actuation of said plunger, an eye shield, a boss extending laterally from said actuator for detachably supporting said shield on said actuator with said shield extending laterally from said actuator substantially coaxial with said nozzle, a plurality of ribs and grooves on and extending longitudinally of said boss, first means in said shield frictionally engageable with said ribs and spacing said shield from said boss whereby said grooves between said boss and said shield admit light and second means on said shield for detachably connecting said shield to said container with said shield substantially coaxial with said plunger and covering said nozzle, said second means comprising threads on said actuator and on said shield for connecting said shield to said actuator, said shield having a rim engageable with said cover to prevent actuation of said plunger when said shield is connected to said actuator by said second means.

2. The dispenser set forth in claim **1** in which said shield comprises a hollow frusto-conical portion and a sleeve portion extending from the smaller diameter end of said frusto-conical portion, said threads being in said sleeve portion.

3. The eyecup dispensing means set forth in claim **1** in which said means for discharging medicament comprises a pump.

4. A spray dispenser for applying a medicament to the human eye and furnishing an illuminated target for attracting the eye to enable the medicament to be introduced into the center of the eye, comprising a container for a medicament, a cover for said container, means mounted on said cover extending into said container and below the level of said medicament for flow of said medicament therethrough and having a plunger for discharging said medicament from said container, an actuator

on said plunger, a boss extending laterally from said actuator having an orifice therein for directing a spray of said medicament laterally from said actuator upon actuation of said plunger, an eye shield, means on said eye shield for detachably connecting said eye shield to said container with said eye shield substantially coaxial with said plunger and covering said boss, and spaced frictionally engageable means on said boss and said eye shield spacing portions of said eye shield from said boss to provide openings extending lengthwise of said boss for passage of light therethrough whereby light is visible from the interior of said eye shield through said openings between said boss when said eye shield is in engagement with the space around the eye.

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RICHARD A. GAUDET, *Primary Examiner.*

W. E. KAMM, *Assistant Examiner.*

EXHIBIT C

April 14, 1970 C. H. COSTELLO 3,506,001

EYE-SPRAYING DEVICE HAVING MIRROR

Filed Nov. 4, 1966

FIG. 1.

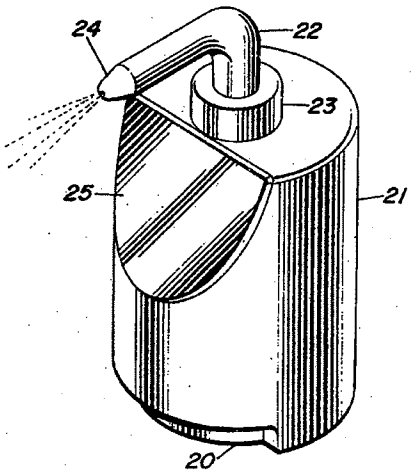
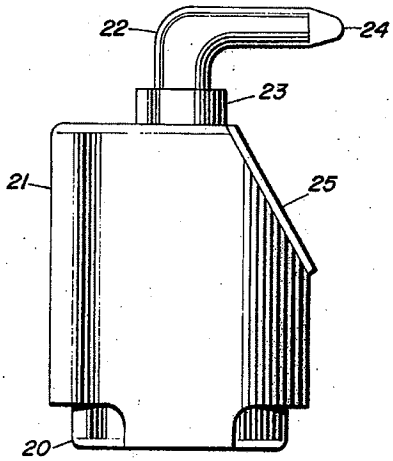


FIG. 2.



INVENTOR

Christopher H. Costello

United States Patent Office

3,506,001
Patented Apr. 14, 1970

3,506,001

EYE-SPRAYING DEVICE HAVING MIRROR

Christopher Hollet Costello, Summit, N.J., assignor to Colgate-Palmolive Company, New York, N.Y., a corporation of Delaware

Filed Nov. 4, 1966, Ser. No. 592,025
Int. Cl. A61m 11/00
U.S. Cl. 128—173 1 Claim

ABSTRACT OF THE DISCLOSURE

The device disclosed herein includes a container for medicated solutions to be administered to the eye, an outlet member associated with the upper portion of the container serving as a directional sprayer, and a mirror mounted and positioned on the device so that the image of the eye is reflected to the user of the device.

The present invention relates to administering medicated solutions to the eye and, more particularly, to spray devices for administering medicated solutions to the eye and provided with a mirror so placed on the spray device that the operator by seeing the reflected image of the operator's eye can direct a spray accurately into the eye which is reflected in the aforesaid mirror.

The conventional methods of administering medicated solutions to the eye are by the use of droppers and eye cups or baths. Since these come in direct contact with the eye, the opportunity for transfer of infection to the dropper or eye cup or to the medicated solution is considerable. The use of a fine spray by means of a nebulizer, squeeze bottle or aerosol devices has greatly reduced the risk of infection. However, considerable difficulty is experienced with these devices in accurately directing the medication into the eye.

The present invention provides for the attachment to the spray device of a small mirror so placed on the spray device that the operator by seeing the reflected image of the operator's eye to be treated can direct the spray accurately into the eye. The mirror also serves to focus light on to the eye. The mirror is postioned on the spray device so that the image of the eye to be treated is reflected and the spray of medicated solution is accurately directed simultaneously. By the use of the mirror on the spray device the spray can be directed into the eye before the reflex action called the wink, takes place.

While the mirror can be mounted on the spray device in any position which with or without movement or adjustment thereof provides a reflection of the eye to be treated which is seen by the operator's eye, it is preferred to mount the mirror on part of the spray device, as will be manifest from the drawings in which:

FIGURE 1 is a perspective of a container having a

button controlling the discharge of the contents of the container mounted in the bottom thereof and having a mirror mounted on the side of the container below the discharge outlet of the dispensing nozzle; and

FIGURE 2 is a side view of the container illustrated in FIGURE 1.

A similar container **21** having a depressible button **20** in the bottom of container **21** is illustrated in FIGURES 1 and 2. As those skilled in the art know an aerosol cartridge containing the medicament is inserted in container **21** and the discharge thereof controlled by button **20**. By pressure upwards on button **20** the contents of container **21** is discharged through tube **22** mounted in closure **23** and thence through nozzle **24**. The container is fabricated from any suitable material, preferably relatively rigid plastic which is molded to provide at one side a plane surface having an angle of about 45 degrees downward with the surface of the top of the container. The mirror **25** is mounted on said plane surface and the closure **23**, bearing the discharge tube **22** is mounted on the container with the nozzle in line with the vertical axis of the mirror **25**.

What is claimed is:

1. A device for administering to an eye a burst of medicament-containing mist, said device comprising a substantially rigid container, a closure member mounted on the container, a discharge tube mounted in said closure, said discharge tube including a dispensing nozzle, and an aerosol means for propelling medicated solution through said discharge tube and out said dispensing nozzle, said container having an inclined plane surface centered on the vertical axis of the discharge tube and making an angle of about 45° downward from the top of the container and a mirror mounted on said inclined plane surface with said dispensing nozzle in line with the vertical axis of the mirror so that reflections of the eye and of the dispensing nozzle can be seen by the user of the device.

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RICHARD A. GAUDET, Primary Examiner

J. D. YASKO, AssistantExaminer

U.S. Cl. X.R.

128—21; 222—106, 192

EXHIBIT D

US005588564A

United States Patent [19]

Hutson et al.

[11] **Patent Number: 5,588,564**

[45] **Date of Patent: Dec. 31, 1996**

[54] **EYE SPRAY MIST DISPENSER**

[76] Inventors: **Clifford L. Hutson**, 4440 J Shadow Hills Cir., Santa Barbara, Calif. 93105; **Robert Demangus**, 1715 N. Pacific Ave., Glendale, Calif. 91202-1108

[21] Appl. No.: **518,143**

[22] Filed: **Aug. 21, 1995**

[51] **Int. Cl.**[6] **B67D 5/40**

[52] **U.S. Cl.** **222/383.1**; 222/523; 222/525; 604/301

[58] **Field of Search** 222/383.1, 523, 222/525, 526, 527; 604/289, 294, 295, 298, 300, 301, 302

[56] **References Cited**

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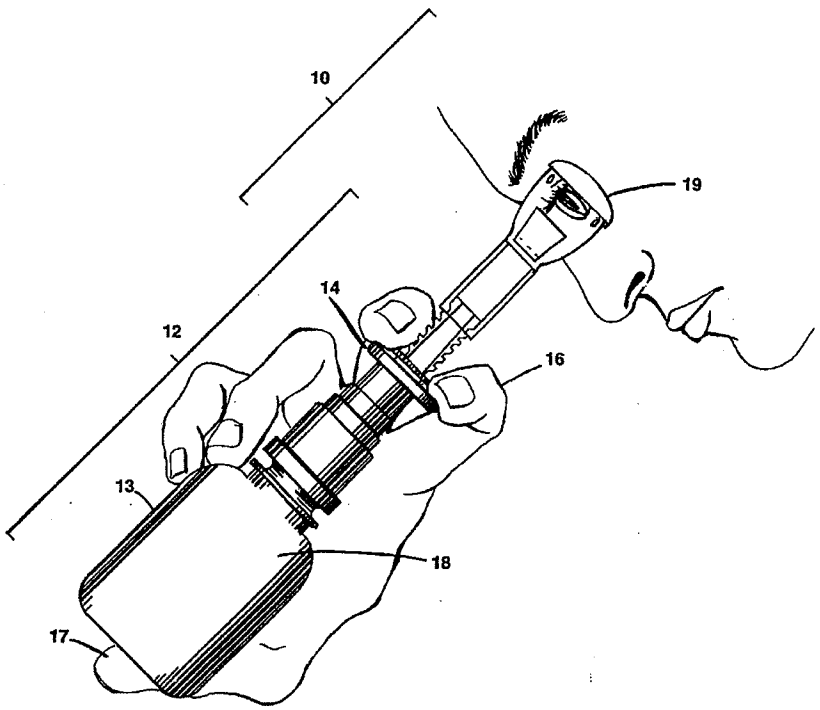
Primary Examiner—Joseph Kaufman
Attorney, Agent, or Firm—Michael G. Petit

[57] **ABSTRACT**

A device including an eye cup portion affixed to one end of an extendible tube portion, the other end of the tube portion is adapted for releasably attaching the tube portion to the nozzle of a spray-mist fluid dispenser. In combination, the device and mist dispenser are operable for controlling the delivery of a fluid to the eye. The device functions both as mask to confine the distribution of the spray mist ejected from the nozzle upon the eye and as a jig operable for adjusting the distance between the mist dispenser nozzle and the eye cup portion of the device. In operation, with the device affixed to a spray mist dispenser nozzle and the tube portion unextended (nozzle closest to the eye), a dense mist is delivered to the cornea and surrounding eye tissues when mist is dispensed. When the tube portion is extended, the spray mist dispenser nozzle is further from the eye cup thereby reducing the density of the spray mist impinging on the eye. The tube portion of the device includes inner and outer concentric tubes and a conical containment chamber affixed to the outer tube and disposed within the eye cup portion of the device. The distance between the wide end of the eye cup and the nozzle engaging end of the tube portion is telescopically adjustable. The containment chamber may be removed from the device to permit the spray nozzle to be positioned nearer the eye. When the tube portion is unextended, the fluid spray mist impinges on the anterior surface of the eye with the greatest force and concentration. For a gentler, finer delivery of spray mist, the containment chamber is preferrably employed and the distance between the dispenser's nozzle delivery orifice and the eye cup portion adjusted and set for comfort and accurate dosimetry.

5 Claims, 3 Drawing Sheets



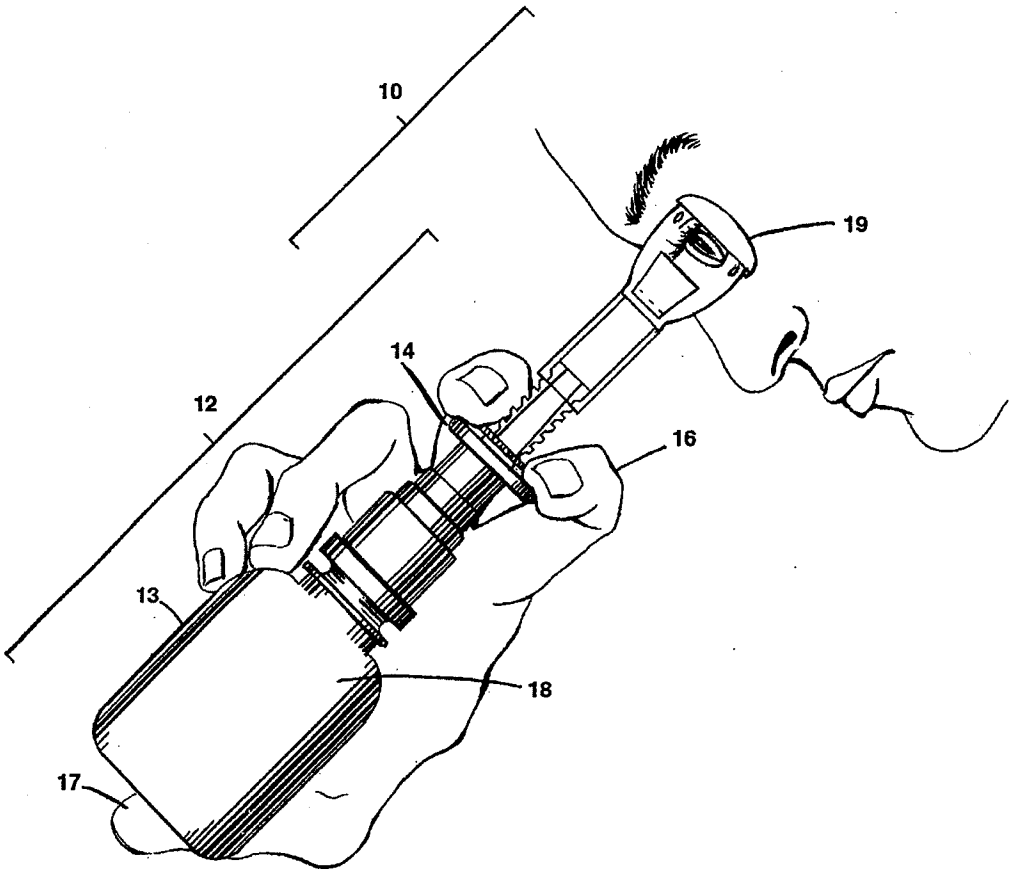


FIG. 1

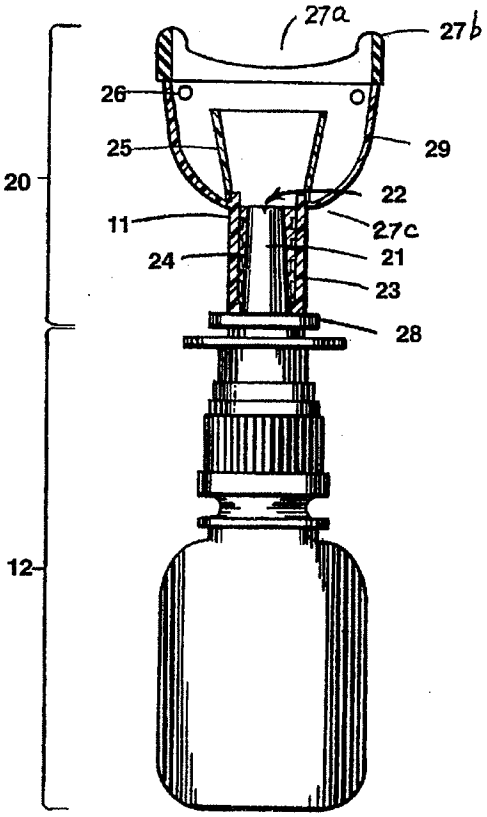


FIG. 2

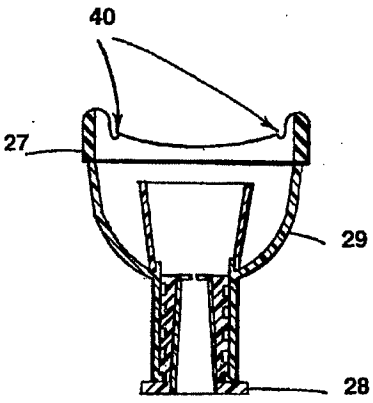


FIG. 4

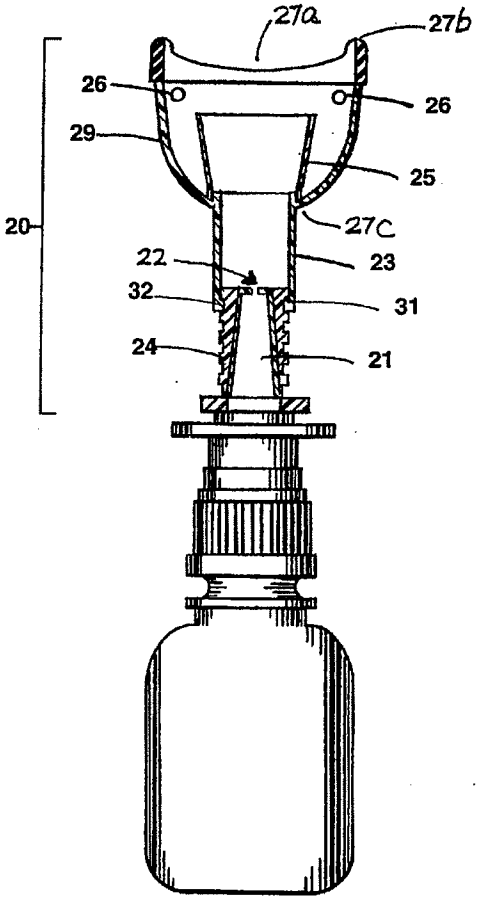


FIG. 3

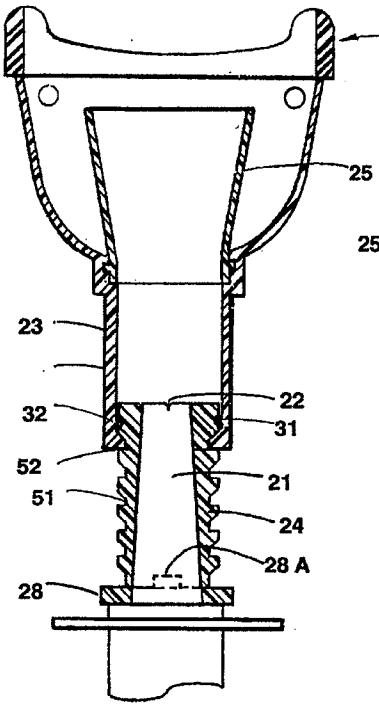


FIG. 5

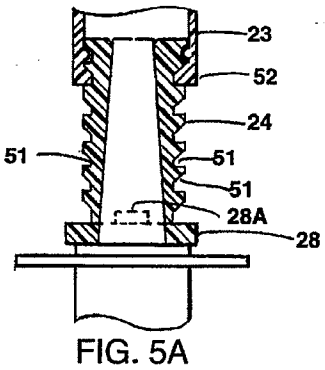


FIG. 5A

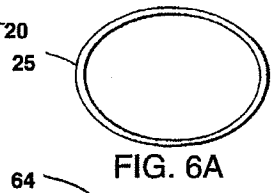


FIG. 6A

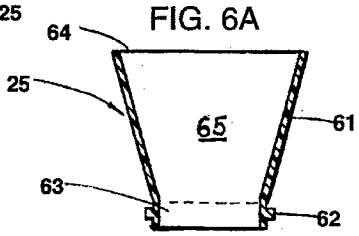


FIG. 6

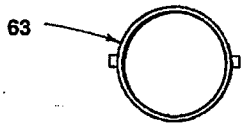


FIG. 7

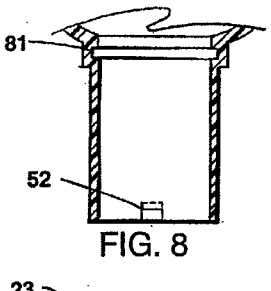


FIG. 8

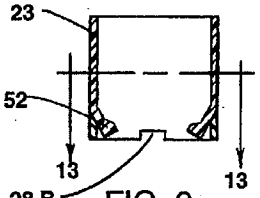


FIG. 9

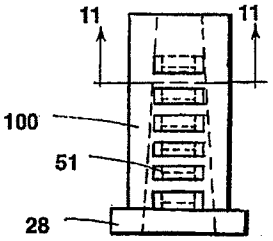


FIG 10

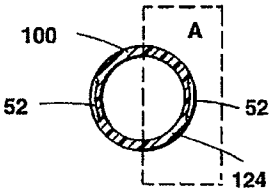


FIG. 11

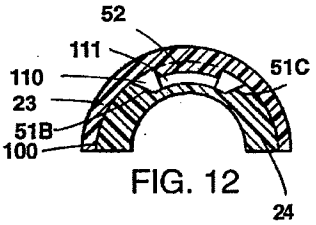


FIG. 12

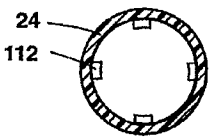


FIG. 13

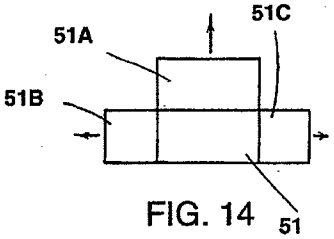


FIG. 14

EYE SPRAY MIST DISPENSER

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a device for topically administering a fluid to the eye and, more particularly, to a device for controlling the self-administered delivery of a fluid spray mist to the eye.

2. Prior Art

Eye treatment solutions are normally self-administered by using either an eye cup or a dropper. The rim of the eye cup is configured to fit snugly against the soft tissue surrounding the eye. Because of the eye cup rim's mating anatomical design, the rim forms a positive seal when placed over the eye and gently pressed against the infra-orbital tissue. In operation, a fluid such as an eye wash solution is placed in the eye cup and the cup is held against the infra-orbital tissue of the eye. The head is tilted back to allow the solution to immerse the eye. The head may also be moved from side to side to allow the solution to be fully distributed over the cornea and the peripheral tissues of the eye.

Another popular device for self-administering a fluid to the eye is a eye dropper. The eye drop solution is delivered directly into the eyes from either a dropper or a dropper type bottle. The person is usually lying down or has the head leaning back during administration. When using the dropper method of administration, one hand of the user pulls the lower lid away from the eye to expose the conjunctiva so that one or more drops of the solution can be introduced thereonto.

While most people can manage either the eye cup immersion or the eye drop method for the self-administration of a fluid to the eye, there is a segment of the population which find these devices and methods awkward or difficult to perform because of various visual and/or physical limitations. For example, individuals having partial or impaired vision, neuromuscular problems, muscular and/or skeletal disease, and those lacking hand/wrist coordination would fall into this group.

In addition to people having serious eye disorders requiring chronic delivery of medication, there are others suffering from eye irritation of a more temporary nature due to exposure to common irritants in both the home and the work place. The most common irritants such as dust and air laden chemicals, industrial particles, smoke, smog, pollen, and chlorinated water, all cause various degrees of eye irritation resulting in much discomfort to the individual. People troubled by dry eyes may also benefit from using an atomized eye wash solution for eye hydration. Such individuals require eye hydration on a frequent and chronic basis in order to attain a degree of eye comfort. In view of the foregoing, there is a need for a spray mist dispenser enabling the controlled and adjustable delivery of a fluid to the eye which is easy to self-administer, even for handicapped people, and does not require the user to assume a recumbent position to effect self-administration.

SUMMARY OF THE INVENTION

In view of the foregoing limitations of present devices for self-administering a fluid to the eye, it is a primary object of this invention to provide an eye solution mist dispenser device which is easy to use and acceptable to a wide range of users, even those with physical and visual limitations.

It is another object of the invention to provide a device as above which is simple in construction and adapted to matingly and releasably attach to and engage the spray nozzle of prior art spray mist atomizers.

It is a further object of the invention to provide a device for controlling the distribution pattern of a fluid mist delivered to the surface of the eye.

It is yet another object of the invention to provide an eye spray mist device which delivers an adjustable and repeatable dose of medicament to the surface of the eye.

One or more of the following embodiments of the present invention satisfies the foregoing objectives. The device has a tube portion comprising concentric inner and outer robes. The inner tube (alternatively) referred to as an "inner sleeve" herein), slides coaxially and telescopically within the outer tube (or alternatively, outer sleeve) and has one end adapted to matingly engage the (usually male) nozzle of a spray mist dispenser such as those currently employed for the nasal administration of drugs. Such prior art spray mist dispensers (for example, the 12H AFRIN® nasal spray pump, Schering Plough Health Care Products, Inc., Memphis, Tenn.) are manually operated by the user and designed to prevent aspiration of contaminated fluids or particles back into the dispenser's treatment solution reservoir. For example, if the spray dispenser's delivery nozzle is tapered, as is the case with most prior art spray mist dispenser nozzles, the interior wall of the end of the inner sleeve attaching to the nozzle (the dispenser end) is preferably tapered to matingly conform to and snugly receive the nozzle of the spray mist dispenser. At the dispenser end of the outer sleeve, two flexible tabs have a portion projecting inwardly are operable for locking engaging mating notches on the outer surface of the inner sleeve to set the length of the telescopically or slidingly adjustable robe portion according to the degree of intensity of the eye spray mist required.

Providing the device with a tube portion having an adjustable length allows the device to function as a jig for adjusting and setting the distance between the spray mist dispenser's delivery nozzle and the rim of the eye cup portion. When the device is attached to a dispenser nozzle, extension of the tube portion moves the nozzle orifice further away from the eye cup portion and thus, when in use, the eye. Once the desired extension of the tube portion is reached, the tabs affixed thereto are locked in position by rotating the outer sleeve until the elastically flexible tabs engage a correspondingly spaced pair of mating notches on the inner sleeve. Readjustment of the length of the tube portion of the device is accomplished by rotating the outer tube either to the fight or to the leer until the tabs disengage from the notches on the inner tube, then sliding the outer tube to a new extension followed by a second rotation to engage the tabs with a new pair of notches. The device, when used in combination with a spray mist dispenser, enables the use of the spray mist dispenser to self-administer fluids such as eye wash solution to the eye. The compact size and ease of operation of the device makes it particularly useful for self-administration of fluids to the eye by individuals having physical and visual limitations.

The features of the present invention believed to be novel set forth with particularity in the appended claims. However, the invention itself, both as to organization and method of operation together with further objects and advantages thereof may be best understood by reference to the following description taken in conjunction with the accompanying drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a preferred embodiment of the present invention.

FIG. **2** is a partially cutaway side view of the embodiment of FIG. **1** showing the attachment of the device to a (prior art) aerosol dispenser.

FIG. **3** shows the device in accordance with FIG. **2** with the outer tube of the tube portion fully extended with respect to the inner tube.

FIG. **4** is a partially cutaway side view of an alternate embodiment of the device showing vent slots in the eye cup portion.

FIG. **5** is a vertical cross-sectional view of the embodiment of FIGS. **1** and **2** in accordance with the present invention showing the inner sleeve of the tube portion of the device attached to and matingly engaging the spray nozzle of a prior art dispenser.

FIG. **5**A is an enlarged view of the tube portion showing a tab on the outer sleeve engaging a notch or detent rest on the inner sleeve.

FIG. **6** is a cross-sectional vertical view of the spray mist containment chamber.

FIG. **6***a* is a top view (in the direction of the broad arrow **6***a* in FIG. **6**) showing the anatomically conforming shape of the delivery end of the chamber.

FIG. **7** is a bottom view of the spray mist chamber.

FIG. **8** is a vertical cross-sectional view of the outer sleeve of the tube portion showing the flexible tabs which engage the notches on the concentric inner sleeve of the tube portion of the device.

FIG. **9** is a vertical cross-sectional view of a portion of the outer tube showing the flexible detent tabs projecting inwardly when relaxed.

FIG. **10** is a perspective front view of the inner tube showing with the notches which function as detent rests for the tabs.

FIG. **11** is a cross-sectional view of the inner tube of FIG. **10**, taken along section line **11**—**11** showing the flexible detent tabs engaging the detent rests.

FIG. **12** is an enlarged view of the boxed portion of FIG. **11**.

FIG. **13** is an end view of the portion of the inner sleeve which matingly engages the nozzle of a prior art dispenser.

FIG. **14** is a side view of a notch or detent rest.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A preferred embodiment of the device of the present invention is shown in FIG. **1**. The device **10**, which may alternately be referred as a spray mist dispenser shield, is shown assembled and removably attached to the delivery tube or of a prior art hand pump type spray mist dispenser **12** (which may be alternatively referred to herein as an "atomizer", a "micromizer" or an "aerosol dispenser"), which dispenser may be releasably attached to a refillable fluid container **13**. In FIG. **1**, the tube portion of the device **10** is shown in its fully extended position. In operation the eye cup portion **11** of the device **10** is placed over the user's infra-orbital area **19** and is held in position with the thumb **17** of the person's right hand placed under the solution container **13** and with the first finger **16** and second finger **16** placed on the pump activator flange **14**. When finger pressure is applied by the fingers to the pump activator flange **14**, a spray mist is expelled through an escape orifice **22** in the nozzle or delivery tube **21**, thereafter to pass through the inner and outer tube assembly **23** and through the eye cup **11**. When the device is fully extended, this action provides for a fine spray mist treatment solution to be delivered to the eye.

A partial side view of a preferred embodiment of the present invention is shown in FIG. **2**. The device **20** is shown in releasable mating engagement with the nozzle **21** of a (prior art) aerosol dispenser **12**. The device **20** is shown with the tube portion in a retracted, unextended position. The device **20** is removably attached to the atomizer nozzle **21** by a friction fit between the nozzle **21** and the inner tube **24** of the device. Alternatively, an attachment means such as a detent rest or detent on the inner tube **24** can be employed to matingly engage a detent rest or detent on the nozzle **21** of a prior art dispenser as shown in FIG. **5** and **13**. The eye cup portion **29** of the device is generally characterized as a hollow hemi-ellipsoid having an open elliptical end **27***a* having a skin-contacting rim **27***b* and a circular open end **27***c* opposite thereto. The eye cup portion **29** may be either removably attached to or permanently affixed to the outer tube **23** at the base **29** of the eye cup portion **11**. The base **28** of the inner tube **24** is tapered on its inner surface to matingly conform to the tapered contour of the outer surface of the (prior art) dispenser nozzle **21**. The mating engagement between the base **28** of the inner tube and the delivery nozzle **21** provides sufficient friction to prevent accidental disengagement of the device **20** from the nozzle **21**. The skin-contacting rim **27***b* of the eye cup **29** is shaped to conform to the soft tissue surrounding the eye and to serve as a directional guide, as well as a seal, during delivery of a spray mist to the eye. The eye cup margin or rim **27***b* is preferably thicker than the wall of the eye cup **29** presenting a round, smooth, comfortable surface to the tissue surrounding the eye.

On the from surface of the eye cup **29** are two vent holes **26**. These holes serve to relieve air pressure on the cornea of the eye which pressure may be created during the placement or removal of the device against the infra-orbital tissue. The spray containment chamber **25** is a (preferably molded) member shaped as the frustum of a cone and having means at the containment chamber's small diameter (distal) end for removable attachment to the interior of the eye cup **29** at its circular base. The purpose of the containment chamber **25** is to confine the delivery of the spray mist into a solid angle so that the mist may be delivered primarily to the cornea of the eye rather than to the general orbital area. The device **20** can be used to deliver fluid to the eye either with or without the spray mist chamber **25**.

In FIG. **3**, the end of the outer tube **23** to which the eye cup is attached is shown fully extended with respect to the base **28** of the inner tube. The inner tube **24** of the device **20** is removably seated on, and in mating engagement with, the (prior art) delivery nozzle **21**. The interior cylindrical surface of the wall of the inner tube **24** is, as discussed earlier, tapered or otherwise shaped to conform to the exterior surface of the delivery nozzle **21** (prior art). The exterior surface of the inner tube **24** is cylindrical and dimensioned to slide within the outer tube **23**. The maximum extension of the outer tube **23** is established by a travel limitation means such as a detent **31** on the outer surface of the inner tube **24** engaging a detent rest at **32** which may be a circular notch encircling the inner surface of the outer tube **23**, to prevent further extension and disengagement of the inner and outer tubes.

An alternate embodiment of the device of FIGS. **2** and **3** is presented in FIG. **4** wherein vent slots **40** in the rim **27** of the eyecup **29** are used to prevent pressure from building within the eye cup in place of the vent holes **26** in the eye

cup. The vent slots **40** are molded in the margin **27** of the eye cup and serve the same purpose as the vent holes **26**.

A vertical cross-sectional view of a first embodiment of the device **10** of FIG. **2** which presents the main features representative of the present invention is shown in FIG. **5**. In this embodiment **20**, the inner tube **24** is shown mounted on a (prior art) atomizer nozzle **21**. A portion of the outer surface of the inner tube **24** has a plurality of detent rests **51** arrayed thereupon. The detent rests **51** are preferably notches or similar indentations in the outer surface of the inner tube dimensioned to lockingly receive tabs **52** affixed to and projecting inward from the outer tube **23**. The detent rests **51** and detent tabs **52** (shown in greater detail in FIGS. **5A**, **8**, **9** and **14**), enable the intensity or dose of the spray mist delivered to the eye (or a portion thereof) to be reproducible by providing means for fixing the distance between the nozzle **21** and the rim **27** of the eye cup **20** for both comfort and accurate dosimetry. The outer tube **23** is shown fully extended and locked into position by flexible tabs **52**, which are shown in greater detail in FIG. **8** and FIG. **9**. In FIG. **5** and FIG. **5A**, the base **28** of the inner tube **24** has a projection **28A** extending upward to matingly engage a recess **28B** (FIG. **9**) in the base of the outer tube **23**. This provides for the outer tube **23** to be properly positioned for extension, when required by the user. It also provides for the outer tube **23** to be properly positioned and locked in alignment for extension, when required by the user. It also provides for easier operation of the device by a user who has impaired vision or hand wrist coordination.

FIG. **5A** is an enlarged view of the inner tube **24** showing the detent rests arrayed along the length of the outer surface of the inner tube. Detent rest **51**, which receives the detent **52** (the flexible tab at the base end of the outer tube **23** shown in FIG. **9** at **52**), serves four functions as shown in FIG. **14**. The abrupt shoulder of the detent rest **51** prevents the accidental downward (collapsing) movement of the outer tube **23**. The incline plane **51A** portion of the detent **51** allows vertical movement when further extension of the device is required. The horizontal or lateral incline planes **51B** and **51C** provide means for the sliding, reversible disengagement of the flexible tab detents **52** from the detent rests **51** by the user by manually rotating the eye cup and the outer tube **23** relative to the inner tube. This rotation brings the flexible detent tabs **52** out of the notches and into contact with a portion of the inner tube having a smooth outer surface **100** (FIG. **11**) so that the outer tube **23** can slide freely in relation to the inner tube **24**. When the device is fully extended as shown in FIG. **5** and FIG. **5A**, the detent **52** engages the upper most travel limiting detent rest on the inner tube **24**. This terminal detent rest is different from the others inasmuch as it does not permit further extension there beyond. All other features of this detent rest are the same; including the release feature of the flexible detent tabs **52** from the detent rest by rotation of the eye cup which is affixed to the outer tube **23**. As mentioned above, such a rotation causes the flexible detent tabs to ride up and out of the detent rest and brings the tabs into contact with the smooth outer surface **100** of the inner tube **24**. In this position, the outer and the inner tubes may be moved telescopically for retraction or extension. section line **11—11** of FIG. **10** with the flexible detent tabs **52** seated in the detent rests. FIG. **12** provides a cross-sectional view of the inner tube **24** and the outer tube **23** with the flexible detent tab **52** engaging a detent rest at **111**. The spaces **110** at the fight and the left of the flexible detent tab **52** and the lateral incline spaces **51B** and **51C** as shown in FIG. **14** permits the fine adjustment of the eye cup either to the right or to the left when it is brought into contact to the orbital area. This adjustment feature is important in order to accommodate those users who might have a problem with the hand wrist coordination or some other physical limitation.

FIG. **8** shows the flexible detent tab **52** at the nozzle end of the outer tube. FIG. **9** shows a saggital of the flexible detent tabs **52** on the outer tube in an unstressed condition: that is, as they appear when the inner tube wall is not pressing on the detent tab, showing a slight deflection inwardly so that the internal ridges of the flexible detent tabs **52** will engage and seat within the detent rest, as the tabs slide along the outer surface of the inner tube **24**.

FIG. **13** shows cross section of the inner tube **24**, at its base areas and detents at **112** to secure the inner tube in place to the base of the delivery tube **21**, detent rest not shown (prior an).

Returning now to FIG. **6** which is a cross-sectional view of the spray mist chamber **25**, a further embodiment is shown. FIG. **6A** shows an embodiment of the containment chambers having an elliptical eye-facing open end to conform to orbital area **19**. FIG. **7** shows the base of the spray mist chamber **63** to be cylindrical in shape. In FIG. **6**, the wall **61** of the spray mist chamber is seen to diverge, the open end **64** terminating into either an elliptical shape as shown in FIG. **6A** or a circular shape. Changing the shape of the containment chamber creates a greater or smaller internal space **65** for confining the spray mist as it fans out before it reaches the eye area.

The tube portion of the device can be telescopically retracted to its most compact position, placing the spray nozzle at the nearest position to the eye. When the tube portion is completely retracted, the outer tube is rotated until an indentation on the nozzle end of the outer tube engages an indexing tab projecting from the base of the inner tube. This locating and locking device serves to position the outer tube in alignment so that when extension of the tube position is required, the flexible detent tabs **52** will be in the correct position to engage the notches or similar detent rests on the outer surface of the inner tube. This automatically places the assembly in alignment for extension.

The device is preferably sterilizable and compact for portability. The eye wash solution reservoir, if the device is permanently affixed to and an integral part of, a fluid mist dispenser is preferably small and refillable. The portable, compact unit is ideal for users who require frequent eye hydration, for home use, a larger version utilizing the same basic principles of design of the smaller portable unit but having a larger eye wash reservoir may be preferable.

Cleanliness of the eye spray mist dispenser device is of the utmost importance to prevent introducing foreign matter such as dust particles, and other debris into the eye. The most important concern is preventing any pathogens, including fungi, yeast, bacteria and viruses from contaminating the solution and/or the mist contacting surfaces of the device which could cause an infection of the eye. The user should take certain precautions to keep the eye spray mist dispenser device clean and free from contaminated material. Care should be exercised to prevent the fingers from touching the orifice of the dispenser nozzle. Rinsing the device with water before and after use is recommended. At intervals, a more complete maintenance should be done by a disassembly of the component parts so each could be cleaned separately. The device is preferably stored in a dust proof container.

There is a large segment of the population that suffers from dry eye syndrome and require frequent eye hydration. Such individuals require treatment a number times a day to

attain an acceptable degree of eye comfort and the device described herein above is particularly useful for such people.

While particular embodiments of the present invention have been illustrated and described, it would be obvious to those skilled in the art that various other changes and modifications can be made without departing from the spirit and scope of the invention. It is therefore intended to cover in the appended claims all such changes and modifications which are within the scope of this invention.

What we claim is:

1. A device operable for controlling the delivery of a fluid mist discharged from the ejection nozzle of a spray mist dispenser to a person's eye comprising:

(a) a hollow hemi-ellipsoidal eye cup having a substantially elliptical proximal open end dimensioned to encircle a person's eye and having a skin-contacting rim on said open end contoured to anatomically conform to infra-orbital tissue adjacent to the person's eye and a distal circular open end;

(b) an axially adjustable tube portion comprising a cylindrical outer tube concentrically overlying a cylindrical inner tube, and having an axial mist-conducting lumen coextensive therewith, said outer tube having a proximal end attached to said eye cup to provide fluid communication between said mist-conducting lumen and said distal circular open end of said eye cup and a distal end, said inner tube being slideably disposed within said outer tube and having a proximal end and a distal end, said distal end of said inner tube including attachment means adapted to releasably attach to the nozzle of the spray mist dispenser, said mist-conducting lumen providing a conduit having an adjustable axial length operable for conducting a fluid mist from said distal end of said inner tube to said proximal end of said outer tube.

2. The device of claim 1, wherein said proximal end of said outer tube of said tube portion is rigidly affixed to said circular open end of said eye cup.

3. The device of claim 1 wherein said tube portion further comprises locking means operable for releasably locking said telescopically adjustable tube portion at a preferred length.

4. The device of claim 1 wherein said eye cup further includes a flow channel operable for conducting gas therethrough releasing excessive pressure within the eye cup when said proximal end and said distal end of said eye cup are occluded.

5. The device of claim 2 wherein said eye cup further includes means operable for maintaining ambient pressure within the eye cup when said proximal end and said distal end of said eye cup are occluded.

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